GOVERNMENT OF INDIA
SCIENCE AND TECHNOLOGY
LOK SABHA

UNSTARRED QUESTION NO:3741
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Development of New Drugs
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Will the Minister of SCIENCE AND TECHNOLOGY be pleased to state:

(a) the steps taken by the Government for development of new drugs across the country so far;

(b) the details of the target set and achievements made in this regard, State/ UT-wise;

(c) whether the Government has tied up with some foundation/agencies in this regard; and

(d) if so, the details thereof along with the results?

Answer

MINISTER OF STATE IN THE MINISTRY OF SCIENCE AND TECHNOLOGY AND MINISTER OF STATE IN THE MINISTRY OF EARTH SCIENCES
(SHRI Y.S. CHOWDHARY)

(a) Several Government institutions like CSIR and ICMR labs, companies and academic institutes are undertaking research for the development of new drugs in the country. The areas of research undertaken by these institutions and companies include anti-cancer, anti-tuberculosis, cardiovascular, anti-diabetic vaccines and other biologicals etc. Government has taken several steps for strengthening Research & Development in pharmaceuticals sector through fiscal incentives to R&D units, streamlining of procedures concerning development of new drug molecules, clinical research and new drug delivery systems leading to new R&D set-ups with excellent infrastructure in the field of drug discovery.

The Department of Science & Technology (DST) is supporting drug research through Drugs and Pharmaceuticals Research Programme. This programme supports industry institutional collaborative R&D projects, creating state-of-the-art national facilities in research laboratories and academic institution and soft loan with a simple interest of 3% per annum to pharma industry R&D projects and grant-in-aid to industries in clinical trials for neglected diseases.

Council of Scientific and Industrial Research (CSIR) through its constituent laboratories namely CSIR−Central Drug Research Institute, CSIR-Indian Institute of Chemical Technology, CSIR-Institute of Microbial Technology, CSIR-Indian Institute of Toxicology Research etc has been pursuing R&D activities in the domain of drugs and pharmaceuticals with emphasis on affordable healthcare. In doing so, CSIR efforts are focused on: understanding disease biology; disease diagnostics; drug discovery and development; high end chemistry-based process development for generic drugs; and creating innovative platforms for enhancing the innovation in the domain.

Department of Bio Technology (DBT) has established a Drug Discovery Research Centre (DDRC) − a multi-disciplinary research unit, with a focus on new drug development in 2013 vs. a niche centre of the Translation Health Science and Technology Institute (THSTI). Biotechnology Industry Research Assistance Council (BIRAC) − a public sector unit is also supporting development of new drugs in the areas of diabetes, antimicrobial resistance and neurodegenerative diseases through its different schemes like Biotechnology Industry Partnership Programme (BIPP), Biotechnology Ignition Grant (BIG) and small Business Innovation Research Initiative (SIBRI) by encouraging partnerships between industry and academia.

Technology Development Board (TDB), a statutory body of the Department of Science and Technology provides equity capital or any other financial assistance to industrial concerns and other agencies including R&D institutions attempting commercial application of indigenous or adapting imported technology for wider domestic application in various sector which also includes development of new drugs.

Department of Pharmaceuticals (DOP) notified "National Pharmaceuticals Pricing Policy" with the objective to put in place a regulatory framework for pricing of drugs so as to ensure availability of required medicines − "essential medicines" at reasonable prices even while providing sufficient opportunity for innovation and competition to support the growth of pharma industry.

(b) Following are some of the products developed under the projects supported by the Drugs and Pharmaceuticals Research Programme (DPRP) of DST: (i) BONISTA − Teriparatide Injection (recombinant human parathyroid hormone) for treatment of Osteoporosis; (ii) RHOCLONE - Anti-Rho-D Immunoglobulin Injection (Monoclonal) 300mcg developed for Hemolytic disease of the new born (HDN); (iii) SYNRIAM - a new anti-malarial drug for the treatment of uncomplicated P. falciparum malaria; (iv) Mycidac − a drug developed for advanced Non small Cell Lung Cancer (NSCLC) etc.

At Biotechnology Industry Research Assistance Council (BIRAC) the successful outcomes include clinical development of TRC 150094 for the treatment of cardiovascular risk factors defined by metabolic syndrome and Galnobax for the treatment of diabetic foot

ulcer which have successfully completed Phase II clinical trials. The projects supported for the development of novel inhibitors of fatty acid biosynthesis and DNA gyrase for the treatment of drug resistant bacterial infections have successfully completed animal studies.

Current efforts at Drug Discovery Research Centre (DDRC) are focused on development of SPR113, a lead small molecule under advance preclinical evaluation (IND enabling studies) with the potential to treat MDR/XDR and TDR form of tuberculosis. DDRC has also developed a lead molecule that displays potent activity against HIV-1 infection in cells. The current emphasis is to validate and optimize this lead molecule. It is also developing a lead candidate with activity against cardiac hypertrophy.

(c) & (d): Government supports projects to Government funded labs and institutes, academia and Indian Pharma Companies.

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